

REMARKS

Status of the Claims

Claims 1, and 10-19 are pending. Claims 12-16 are withdrawn. In the above amendment, claim 1 is amended and claims 17-19 are added. Support for the new claims can be found in the Specification and original claim 11.

Applicants have also amended claim 1 to remove certain species of compounds, by proviso, specifically to ensure the claims do not encompass compounds or compositions comprising such compounds that may have been previously disclosed. The proviso is supported by the Specification as filed, as Applicants are simply claiming less than the full scope of their disclosure – a perfectly legitimate exercise since it is for the inventors to decide what bounds of protection they will seek. Moreover, Applicants respectfully submit that *In re Johnson*, 194 U.S.P.Q. 187 (C.C.P.A. 1977), provides legal precedent for the addition of the proviso.

No new matter is added in the above amendment.

Restriction Requirement

As stated in the previous response, Applicants specifically reserve the right to rejoin the claims of Groups II pursuant to the rejoinder procedures set forth in MPEP § 820.04, upon the allowance of the elected claims of Group I.

Issues Under 35 U.S.C. §112, Second Paragraph

Claims 1 and 10 are rejected under 35 U.S.C. § 112, as allegedly being indefinite. Four separate issues are raised in paragraphs 7-10 in the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Office Action alleges that the definition of R₁₅ is vague because it does not show the attachment point of the methoxybenzene substituent. This issue is moot in view of the above amendment.

The Office Action further alleges that there is insufficient antecedent basis for the term “HET.” This issue is moot in view of the above amendment.

The Office Action further alleges that the claims are indefinite for their use of the term “prodrug.” This issue is moot in view of the above amendment.

Finally, the Office Action alleges that the claims are indefinite because “[t]he definition of R₁₆ is vague and indefinite because it is not clear what the substituent are included are excluded [sic].” This position is respectfully traversed by the Applicants.

A claim is definite within the meaning of 35 U.S.C. § 112, second paragraph, if it sets out and circumscribes a particular subject matter with a reasonable degree of clarity and particularly. See M.P.E.P. § 2173.02. Further, the USPTO is specifically instructed to “allow claims which define the patentable subject matter with a reasonable degree of particularly and distinctness. Id. .

The Federal Circuit, in a long line of cases, has made it clear that the definiteness of claim language must be analyzed not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary skill in the art at the time the invention was made. See, for example, *In re Marosi*, 218 U.S.P.Q. 289 (Fed. Cir. 1983).

Additionally, see *S3 Inc. v. nVidia Corp.*, 259 F.3d 1364, 1369 (Fed. Cir. 2001), where the Court stated: The purpose of the claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not “indefinite” simply because it is hard to understand when viewed with the benefit of the specification.

In the present Office Action, there appears to be no consideration of the specification, which is required, in making the assertion that one of ordinary skill in the art would not be able to make the “relation” discussed in the claim. Applicants do not agree with the implication that one of ordinary skill in the art would not understand the metes and bounds of the claims because “it is unclear what alkyl [or] aryl groups” are claimed. These terms are clearly defined in the Specification (beginning on page 15, for example) and the terms are well known in the chemical arts. The Examiner has cited no objective authority to suggest that the terms alkyl and aryl, when properly analyzed as outlined above, are not reasonably precise enough to comply with § 112.

Additionally, Applicants respectfully note that a broad claim, no matter how broad, is not indefinite for the purposes of § 112, so long as the boundaries of the claim are capable of being understood. In other words, breadth is not indefiniteness. See *In re Miller*, 169 U.S.P.Q. 597 (CCPA 1971).

The Office Action fails to present a proper, adequately supported case of indefiniteness. Reconsideration and withdrawal thereof are respectfully requested.

Issues Under 35 U.S.C. § 112, First Paragraph

Claims 1, and 10 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

One allegation of the Office Action is that claim 1 has the “the presence of undefined groups such as alkyl, aryl...” See page 4 of the Office Action. This is not understood in view of the Specification beginning on page 15, where both alkyl and aryl are clearly defined.

Additionally, one allegation in the Office Action is that claim 1 is not enabled because of “the unknown position of attachment of R₁₅ and R₁₆...” This is not understood in view of the fact that there are only 5 positions available on the ring.

Further, the Office Action states that the level of skill is high, presumably with respect to one of ordinary skill in the art’s ability to understand the scope of the defined terms and to be able to prepare the claimed compounds within the meaning of 35 U.S.C. § 112, first paragraph.

The Office Action fails to offer any objective evidence to suggest otherwise. That is, the Office Action fails to cite or rely on any authority as to why one of ordinary skill in the art cannot make the compounds as claimed without undue experimentation. Of course, it is not necessary that the enablement be such that a person attempting to make or use the invention be successful on the first try. The law of enablement recognizes that some experimentation may be necessary, as long as the amount of experimentation required is not unduly extensive. See *Utter v. Hiraga et al.*, 845 F.2d 993 (Fed. Cir. 1988), citing *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). Optimality is not required.

Additionally, as stated by the Federal Circuit, “Nothing more than objective enablement is required, and therefore it is irrelevant whether [a] teaching is provided through broad terminology or illustrative examples.” *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). Further, the Federal Circuit has specified that the “specification may, within the meaning of 35 U.S.C. § 112, first paragraph, contain a written description of a broadly claimed invention without describing all species that claim encompasses.” *Spectra-Physics Inc. v. Coherent Inc.*, 3 U.S.P.Q.2d 1317 (Fed. Cir. 1987).

In view of the above, and by only offering a subjective view point with no objective evidence, the Office is in effect shifting the burden of persuasion to the Applicant to prove that the specification is enabled. This is not the proper approach. By law a patent application is presumptively valid when filed. Thus, during examination, “[a]s a matter of Patent Office practice... a specification... must be taken as in compliance with the enablement requirement... unless there is a reason to doubt the truth of the statements contained therein...” *In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971). As pointed out by MPEP § 2164.04, entitled “Burden on the

Examiner Under the Enablement Requirement,” case law makes it clear that properly reasoned and supported statements explaining any failure to comply with section 112 are a requirement to support a rejection.

The Office Action has not, in the words of *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971), backed up assertions as to why the truth or accuracy of statements in the Specification are doubted with acceptable evidence or reasoning. MPEP § 2164.05 states that “the examiner should **never** make the determination based on personal opinion.” (Emphasis in original).

As such, the Office Action fails to meet its burden of establishing a showing nonenablement. Thus, Applicants respectfully submit that the rejection should be withdrawn.

Issues Under 35 U.S.C. § 102

Claim 1 is rejected under 35 U.S.C. § 102 as allegedly being anticipated by Shao et al. This rejection is respectfully traversed. However, the rejection is moot in view of the above amendment. Thus, Applicants respectfully submit that the rejection should be withdrawn.

Petition for an Extension of Time

Pursuant to the provisions of 37 C.F.R. §§ 1.17, 1.136(a), the Applicants hereby petition for an extension of time of three (3) months to May 7, 2008 for the period in which to file a

response to the outstanding Office Action. The required fee is authorized with the electronic submission of this document.

The Commissioner is authorized to charge any deficiency or credit any overpayment associated with this amendment to Deposit Account 50-2752.

If the Examiner has any questions concerning this election or the Application in general, he is respectfully requested to contact the undersigned at the number listed below.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Richard S. Myers, Jr.", is positioned above the printed name.

Richard S. Myers, Jr.
Registration No. 42,022
Attorney for Applicant